

Brief Personalized Feedback Intervention for Hazardous Drinking in an HIV Clinic

NCT ID not yet assigned

04/17/19

Study Protocol

1.0 Objectives

The goal of this research is to demonstrate the efficacy of an ambulatory evidence- and computer-based Personalized Feedback Intervention (PFI) among hard-to reach HIV+ hazardous alcohol users in primary care.

Hypothesis 1: The PFI group will show reduced drinking behavior and alcohol-related risky sexual behavior at 3 month follow-up. Hypothesis 2: Effects on alcohol related risky sexual behavior will be mediated by reduction in drinking. Hypothesis 3: Changes in alcohol use attitudes, normative perceptions, self-efficacy for alcohol abstinence, intentions to use, alcohol outcome expectancies, and protective behavior strategies will mediate intervention effects on drinking behavior.

2.0 Background

Rates of hazardous alcohol use among HIV+ individuals is approximately two times of that found in the general population. Hazardous alcohol use contributes to problems with HIV medication adherence, risky sexual behavior, psychological problems as well as rapid disease progression, medication toxicities, organ failure, and poor viremic control and may lead to increased risk of transmission and premature death. If PFI can be successfully transported to the HIV+ populations via primary care and be effective in reducing hazardous alcohol use among HIV+ hazardous alcohol users, then PFI will be shown to be effective in a setting where such hard-to-reach HIV+ hazardous alcohol users are most likely to be engaged.

3.0 Inclusion and Exclusion Criteria

Inclusion Criteria: HIV positive serostatus as confirmed by medical records, after providing consent and completing the HIPAA authorization; AUDIT scores for the last 30 days for women: ≥ 7 and for men: ≥ 8 ; between the ages of 18 and 50 years of age; reading level on the WRAT 4 above 5th grade and proficient in English, although English does not have to be the first language; not currently in an alcohol treatment program.

Exclusion Criteria: Unwillingness to participate; inability (e.g. mental capacity) to provide informed consent and/or HIPAA authorization; current suicidality; psychotic symptoms; currently pregnant; currently receiving treatment to reduce alcohol use; not currently HIV+; AUDIT scores less than 7 for women and 8 for men; under the age of 18 or over the age of 50; reading level below 5th grade; lack of proficiency in English.

Justification: The inclusion of HIV+ individuals with AUDIT scores greater than or equal to 7 for women and greater than or equal to 8 for men represents the target population of the present study. Pregnant individuals and those under the age of 18 and over the age of 50 are excluded because we are interested in reduction of sexual risk-taking behavior and because psychosocial adjustment scores may be influenced by pregnancy and age. Reading level and language

proficiency are inclusion criteria to facilitate understanding of study materials and measures. Psychotic symptoms and current suicidality are an exclusion criterion to ensure that participants are of sound mind to participate willingly. Current treatment in an alcohol program is an exclusion criteria because this may present a confound with intervention outcomes.

Determination: We will employ a one-step screening process. Upon providing consent and completing the HIPAA authorization, participants will be asked questions regarding: their gender, HIV status as confirmed via medical records, if they are between 18 and 50, and whether or not they are pregnant (women). Additionally, they will be directed to complete the AUDIT and asked to disclose whether they are currently in an alcohol treatment program. Furthermore, participants will be assessed for current suicidality and current psychosis. We will also assess their reading level using the Word Reading component of the WRAT-4,. Participants must meet the following criteria in order to be eligible to take the baseline and the intervention: they must be HIV+, be between 18 and 50 years old, not pregnant (for women), not have any current psychiatric diagnosis that would preclude them from participating in our study, able to read at a 5th grade level per the Word Reading component of the WRAT-4, report scores of at least seven for women and eight for men on the AUDIT, not currently suicidal, and not currently in alcohol treatment. Eligible participants will be given the option to either complete the baseline/intervention activities at that time, or to schedule to take it at another time. Participants who do not meet eligibility criteria will be thanked for their time, and dismissed. If a patient endorses current suicidality, a protocol to further assess the level of suicidality is in place.

During baseline, participants will complete a series of questionnaires on a tablet or laptop computer. Upon completion of the survey, participants will randomly receive either the PFI or attention control feedback. A follow-up assessment will be conducted three months after the baseline/intervention, and will include all measures from the initial baseline. The estimated amount of time it will take to complete each component of the study are as follows: the screening session: 30 minutes; baseline/intervention: 60 minutes (including 20-30 minutes for the intervention); and follow-up session: 30-40 minutes.

None of the following populations will be recruited:

- Adults unable to consent and/or HIPAA authorization
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Students for whom you have direct access to/influence on grades

4.0 Vulnerable Populations

N/A

5.0 Number of Subjects

LOCAL:

Expected maximum number of participants to be enrolled and complete baseline appointment: 150

150 participants will allow for statistical analyses to determine group differences between participants randomized to the control (n=75) and treatment (n=75) conditions.

6.0 Recruitment Methods

LOCAL:

Participants will be recruited via referral from the staff and via flyers at each of the study sites. Please see the attached documents for specific scripts/language used in recruitment.

7.0 Study Timelines

The screening assessment will last approximately 30 minutes.

The baseline/intervention appointment will last approximately 1 hour and thirty minutes.

The 3-month follow-up appointment will last approximately 30-40 minutes.

The anticipated duration to enroll study participants is three years.

The estimated date to complete the study is December 2020.

8.0 Study Endpoints

The primary study endpoint will be the completion of the 3-month follow-up session by each of the total number of subjects to be enrolled in the study. The secondary study endpoint will be the completion of data analyses.

9.0 Procedures Involved

At Thomas Street Clinic and Legacy Community Health, potential participants will be referred to an on-site research assistant, who will screen them for study eligibility criteria. Screening procedures are expected to take 30 minutes. Upon providing consent and HIPAA authorization, participants will complete screening procedure. Additionally, relevant information from the participant's medical records will be obtained. Access to participants' medical records will be requested from the participant in order to assess, history of sexually transmitted infection,

and HIV/AIDS disease severity (e.g., T cell count and viral load). Those who meet initial eligibility will be invited to participate in a baseline assessment and intervention. Before the screening assessment begins, each participant will be provided informed consent and complete a HIPAA authorization form. The screening assessment is expected to take approximately 30 minutes to complete, and the baseline procedure is expected to take approximately 30 minutes to complete. Following the baseline assessment, eligible participants will be randomized between an intervention group and a control group. In the same appointment as the baseline assessment, participants in the intervention group will receive a computerized personalized feedback intervention lasting approximately 20-30 minutes, while the control group will receive an attention control information session that will be comparable in focus on health-related behaviors (e.g., nutrition, exercise). We will use behaviors in the attention control feedback that are not associated with study outcomes. Attention control feedback will have text and graphs that are similar in appearance and length (i.e., approximately 20-30 minutes) to intervention feedback. The appointment will conclude with a post-treatment assessment lasting approximately 5 minutes. The total time to complete the baseline assessment, intervention/attentional-control, and posttreatment assessment will be approximately one hour and thirty minutes. Each participant will also be asked to complete a 3-month follow-up assessments that will last approximately 20-30 minutes. The primary analysis strategy for evaluating hypotheses will consist of multi-level regression analyses, (Hierarchical Linear Modeling (HLM) or mixed-effects modeling). With respect to evaluating main effects of experimental conditions on drinking, each participant will provide baseline, post-intervention, and the 3-month follow-up data. Repeated measures data define a two level data structure with repeated responses within-individuals as level-1 and individuals at level-2. The study evaluates an intervention condition against a comparison condition, with changes in perceived norms as a mediator. Specific hypotheses will be tested using specific contrast vectors, using a generalized linear hypothesis framework. Distributional assumptions will be considered and we will incorporate negative binomial or zero-altered count models as needed.

Tasks to be performed:

Each participant will complete a screening process, a baseline assessment, a computerized intervention/attentional control, a post-treatment assessment, and a 3-month follow-up assessment. The screening process will cover certain inclusion/exclusion criteria and record the participant's contact information. The screening process will last 30 minutes. Participants who are eligible will be invited to a baseline appointment, which they may either complete at that time, or schedule on another day that is more convenient. The baseline assessment will last approximately 1 hour and thirty minutes (20-30 minutes for assessment) and including a diagnostic interview and questionnaire measures of demographic information, health status, alcohol treatment history, alcohol use outcomes and modifiers (norms, attitudes, self-efficacy, intentions, expectancies, behavior strategies, motives), sexual behavior, depression/anxiety symptoms, HIV-related symptoms, and HIV-related outcomes (e.g. CD4 count, quality of life). Following

the baseline assessment, participants who are eligible will be randomized to either an intervention group or a control group. In the same appointment as the baseline assessment, participants in the intervention group will receive a computerized personalized feedback intervention (PFI) lasting approximately 20-30 minutes (included in the 1 hour and thirty minutes baseline session), and the control group will receive an attention control information session that will be comparable in focus on health-related behaviors (e.g., nutrition, exercise), also lasting 20-30 minutes (also included in the 1 hour and thirty minutes baseline session). PFI highlights discrepancies between one's own drinking and typical drinking; reframes use in terms of personal, social, financial, and health consequences; and, offers strategies for reducing alcohol use. The content and process of the PFIs will be based on our previously efficacious interventions reducing problematic drinking behavior among other populations (Carey et al., 2007; Cunningham et al., 2010) and increasing non-alcohol-related health-protective behavior (e.g. condom use; medication adherence) among HIV+ individuals (Abamecha, Godesso, & Girma, 2013; Janepanish, Dancy, & Park, 2011; Saal & Kagee, 2012; Westmaas et al., 2012). PFI highlights discrepancies between one's own drinking and typical drinking; reframes use in terms of personal, social, financial, and health consequences; and, offers strategies for reducing alcohol use. The feedback is non-confrontational in tone, seeks to increase motivation to reduce drinking and is based on the information provided during the baseline assessment. The PFI condition will take 20-30 minutes to complete. Each component of the feedback will be presented on its own screen. Time on each feedback component section will be tracked as one measure of feedback participation. Feedback will be programmed using Qualtrics and will be hooked into the baseline's data entry module, thereby allowing data to be imported directly from the survey into the feedback. Attention control information will be comparable in focus on health-related behaviors (e.g., nutrition, exercise). We will use behaviors in the attention control feedback that are not associated with study outcomes. Attention control feedback will have text and graphs that are similar in appearance and length (i.e., 20-30 minutes) to intervention feedback. The initial appointment will conclude with a post-treatment assessment lasting approximately 5 minutes that will assess 1) the degree to which the participant has processed the PFI; and 2) the participant's current readiness to change alcohol use.

Each participant will also be asked to complete a 3-month follow-up assessment that will last approximately 20-30 minutes and will assess the study outcomes or mediators from the baseline assessment. Based on the feedback provided in the intervention, it is expected that the treatment group will modify their drinking behavior to be more closely aligned with typical drinking patterns, and that the reduction in alcohol use-related problems will result in less risky sexual behaviors associated with alcohol use and increased HIV medication adherence.

Measures:

Screener: Contact information (e.g. phone number; email address); age; date of birth; gender; HIV status; dosage of anti-HIV drugs; other medications' dosage;

pregnancy status; whether expect to re-locate within the next 3 months (for follow-up purposes); Alcohol Use Disorders Identification Test (AUDIT; e.g. Have you or someone else been injured as a result of your drinking?); treatment history to reduce alcohol use (2 items: current and past); Wide Range Assessment Test (WRAT), 3rd Edition-Word Reading subtest (Stone et al., 1995). Initial and Follow-up appointments: Demographics (e.g. age, sex, education); Graded Chronic Pain Scale (e.g., In the past six months, how intense was your worst pain, rated on a 0 to 10 scale where 0 is “no pain” and 10 is “pain as bad as could be?”); Hurricane Harvey Experience (e.g., Did your home get flooded?); HIV/AIDS Stigma Scale (e.g. I feel guilty because I have HIV/AIDS); HIV medical history (e.g. date of transmission, method of transmission, CD4+ count); ACTG Adherence Questionnaire (e.g. Number of HIV medication doses missed within the last 2 weeks?); WHO HIV Quality of Life (e.g. How would you rate your quality of life?); Medical History and Present Medical Condition Questionnaire (e.g. asthma, high blood pressure, COPD); the psychosis portion of the Mini International Neuropsychiatric Interview 6.0.0 (MINI 6.0.0); Drinking Motives Questionnaire (DMQ); Protective Behavior Strategies (PBS); Alcohol Outcome Expectancies (CEOA); Drink Refusal Self Efficacy Questionnaire-Revised (DRSEQ-R); Alcohol Use Attitudes; Suicide Behaviors Assessment (SBA); Drinker Inventory of Consequences (DRINC); Inventory of Depression and Anxiety Symptoms (IDAS) (only the General Depression, Social Anxiety, and Panic subscales: 33 items); AUDIT; Timeline Follow-Back (TLFB; for all substances); 11 items); Daily Drinking Questionnaire (e.g. On average, during the last month, how often have you consumed alcohol?); Quantity/Frequency/Peak Alcohol Use Index (e.g. Think of the occasion you drank the most this past month. How much did you drink?); Short Inventory of Problems (SIP2R; I have been unhappy because of my drinking); Sex-related Alcohol Expectancies Scale (e.g. After a few drinks I have sex with people with whom I wouldn't have sex if I were sober.); Sexual Experiences Inventories (e.g. Have you ever had anal sexual intercourse?); Risky Sexual Behavior and Alcohol-Related Risky Sexual Behavior (e.g. You said you had anal sex ___ times in the past 3 months. Of the ___ times, how many times did you consume alcohol before or during the sexual encounter?); Drinking Norms Rating Form (e.g. Consider a typical week during the last month. How much alcohol, on average (measured in number of drinks), does a typical male/female about your age drink on each day of a typical week?); Intentions to Drink (e.g. On average, during the next month, how often do you intend to consume alcohol?); *Readiness to Change Questionnaire* (e.g. [Likert response to:] My drinking is a problem sometimes.); Participant Locator Form (PLF; e.g. contact info for relatives could get in touch with the participant if s/he moves between baseline and 3 month follow-up); Participant Contact Form (PCF; e.g. contact information); Behavior and Symptom Identification Scale (BASIS-24; During the past week, how much difficulty did you have ... managing your day-to-day life?); .

10.0 Setting

The research study will be conducted at Thomas Street Health Center and Legacy Community Health.

Screening sessions will be conducted when a participant calls or goes up to a research assistant at either the Thomas Street Health Center or Legacy Community Health expressing interest in the study. Screening sessions will last approximately 30 minutes. All other assessments will take place via computerized questionnaires and a diagnostic interview conducted in person at the study location in a room that has been reserved for study use. The setting will likely be familiar to participants and will mitigate discomfort. Data will be entered using computer-delivered surveys programmed using Qualtrics.

Unless otherwise noted, behaviors will be reported over the past three months to prevent overlap in assessment time points and to enhance recall. Given that all measures are subject to error and limitations, multiple measures will be included for each core construct to ensure our ability to effectively evaluate each aim. The assessments will begin with a series of practice questions such that participants can become familiar with responding to different question types (e.g., Likert items, open response questions). Participants who are notified of their eligibility at the end of the screening assessment will immediately be routed to the baseline survey, if they are able to complete baseline procedures at that time.

Confidentiality will be maintained by conducting assessments in a private office and by having participants complete computerized surveys on a password-protected laptop, with information stored according to the participant's study number. All participant information will be de-identified, and the consent form and reimbursement form will not record the participant's study number. Questionnaires completed via Qualtrics will also be coded with an arbitrary study number. This online system is password protected, such that only personnel affiliated with the study are able to access the data. The diagnostic interview will be audiotaped to allow for the PI to cross-check diagnoses with the principal investigator. Audio recordings will be deleted once they have been reviewed by the PI. Importantly, these audio recordings will only be coded with an arbitrary study number and not identifying information (e.g., name, date of birth). If during the baseline assessment a participant provides responses that suggest suicide risk, referral will be made to the psychiatric clinic at the Thomas Street Health Clinic and Legacy Community Health. Additionally, the Principle Investigator (PI), a clinical psychologist, will be informed immediately if a patient is a suicide risk and the PI will work closely with staff at Thomas Street Health Clinic or Legacy Community Health to respond to the issue.

11.0 Risks to Subjects

Risk for emotional distress while completing questionnaires and diagnostic interview may occur and will likely be minimal and temporary. Referrals for psychiatric care will be made if deemed appropriate.

12.0 Potential Benefits to Subjects

Participants who are randomized to the computerized personalized feedback intervention may benefit from receiving feedback about how their alcohol use and alcohol-related risky sexual behavior compare to age-based normative behavior, which may serve as a motivator to reduce risk-related behavior by utilizing protective behavior strategies presented by the intervention. Participants who are randomized to the computerized attentional control may benefit from the health-related information presented to them (e.g. nutrition, exercise).

13.0 Withdrawal of Subjects

Participants will be withdrawn for not arriving to study appointments.

14.0 Costs/Payments to Subjects

Participants will be provided \$50 for the baseline assessment, and \$40 for the 3-month follow-up.

15.0 Confidentiality

Consent forms with identifying information (names, address) will be filed separately from the actual study data, under lock and key. A password protected computer file will contain information linking participant names to their assigned numbers. Only the researchers will have access to this information. Questionnaire packets, when applicable, will also be stored under lock and key. All data will have personal identifiers removed and the data will be aggregated through qualitative analyses.

16.0 Provisions to Protect the Privacy Interests of Subjects

Private rooms will be used for all assessments.

17.0 Informed Consent Process

Eligible participants will be offered informed consent by an on-site research assistant at Thomas Street Clinic and Legacy Community Health, who will be trained to go through eligibility criteria and the consent form with participants. Additionally, participants will complete a HIPAA authorization form. For those who are eligible to participate in the study, the baseline appointments will begin with the research personnel describing the study to each participant via the consent form, which will be provided to the participant. The research assistant/interviewer will explain the study purpose, procedures, risks, benefits, and voluntary basis of participation to each participant.

18.0 Process to Document Consent in Writing

The study will be following “SOP: Written Documentation of Consent (HRP-091).”

19.0 Data Management

Data will be collected using self-report questionnaires and clinical diagnostic interviews. All measures will be completed confidentially, using a secure encrypted web server, will be identified with a unique patient identification number generated for research purposes only. Consent forms with identifying information (names and study code) will be filed separately from the actual study data, under lock and key. A password protected computer file will contain information linking participant names to their assigned numbers. Only the researchers will have access to this information. Questionnaire packets, when applicable, will also be stored under lock and key in a filing cabinet. All data will have personal identifiers removed and the data will be aggregated through qualitative analyses. All paper copies of study data will be stored in locked filing cabinets in Dr. Carla Sharp's laboratory located in the Texas Institute for Measurement, Evaluation and Statistics (TIMES) on the 4th floor of the Health and Biomedical Sciences building. All digital study data that is collected via Qualtrics will be stored using encryption and password protection on the TIMES server, which is compliant with HIPAA and allows for the separation of participant identifying information and participant study data. Audio recordings and interview data will also be stored on the encrypted and password-protected University of Houston server maintained by TIMES. All study data will be stored for a minimum of 3 years following the conclusion of the study, which will occur when all data analysis is finished.

20.0 Sharing of Results with Subjects

Study results will not be shared with participants.

21.0 Resources

Drs. Sharp and Zvolensky have extensive experience recruiting among HIV+ adults. Dr. Neighbors has extensive experience with the design and testing of personalized feedback interventions.

22.0 Additional Approvals

N/A

23.0 HIPAA

We will be obtaining and using individually identifiable health information associated with a HIPAA-covered component or entity in the course of the research. Access to this information is necessary to confirm participants' HIV status, as well as to determine T-4 cell count and viral load.

This protected health information (PHI) will be filed separately from the actual study data, under lock and key. A password protected computer file will contain information linking participant names to their PHI. Only the researchers will have access to this information. All data will have personal identifiers removed and the data will be aggregated through qualitative analyses 3 years following the conclusion of the study. All PHI will be stored in locked filing cabinets in Dr. Carla Sharp's laboratory located in the Texas Institute for Measurement, Evaluation and Statistics (TIMES) on the 4th floor of the Health and Biomedical Sciences building. All PHI will be stored for a minimum of 3 years following the conclusion of the study, which will occur when all data analysis is finished. PHI information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

Given that the purpose of this study is to reduce alcohol-related harms among those who are HIV+, it is necessary to ensure that we are targeting the correct population. Therefore, this research cannot be practicably conducted without access to use of this PHI.

PHI will not be accessed prior to subject authorization.

24.0 Statistical Analysis Plan

The primary analysis strategy for evaluating hypotheses will consist of multi-level regression analyses, (Hierarchical Linear Modeling (HLM) or mixed-effects modeling). With respect to evaluating main effects of experimental conditions on drinking, each participant will provide baseline, post-intervention, and the 3-month follow-up data. Repeated measures data define a two level data structure with repeated responses within-individuals as level-1 and individuals at level-2. The study evaluates an intervention condition against a comparison condition, with changes in perceived norms as a mediator. Specific hypotheses will be tested using specific contrast vectors, using a generalized linear hypothesis framework. Distributional assumptions will be considered and we will incorporate negative binomial or zero-altered count models as needed.